

## **Remarks**

Claims 1-11 were pending in this application. None of Claims 1-11 have been amended. Claims 12-20 have been added. The new Claims added herein do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the instant Specification.

### ***Claim Rejections under 35 USC § 102***

#### **Anticipation by Sage**

The Examiner has rejected Claims 1-11 are under 35 U.S.C. §102(b) as being anticipated by Sage et al. in U.S. Patent 5,957,895, issued Sept. 28, 1999 (hereinafter, “Sage”). The Examiner Alleges (emphasis added):

*“Regarding claims 1, 6 and 7 Sage teaches an infusion device comprising a fluid reservoir (50) having at least one flexible wall (1 02 or 1 04), a needle (external tip portion of 54), a Belleville spring (102 or 104), and a pin (internal end portion of 54).*

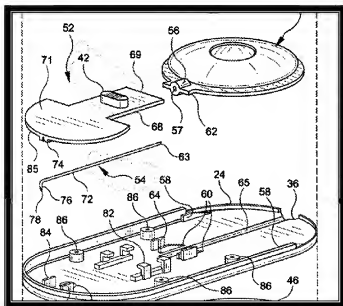
*Regarding claims 2 and 8, there is a tactile indication that the pin is disengaged from the central aperture of the Belleville spring.*

*Regarding claims 3-5 and 9-1 1, disengagement occurs automatically when the user operates a push button (42), and includes removing a guard or interlock (52)”.*

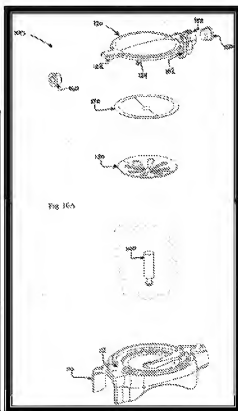
The operation of the Sage device involves a fluid-access needle 54. The needle 54 of Sage, which the Examiner referred to the internal end portion as a “pin”, has specific structure as discussed in Col 7, lines 35-45, for accessing the contents of the reservoir. It is understood from the disclosure of Sage that the “pin” [needle 54] referred to by the Examiner is used as a fluid transfer means, which has a completely different principle of operation than the pin of the device as presently claimed by the Applicants. Thus, the needle 54 of Sage is not equivalent in structure or usage to pin 140 of the Applicants’ disclosure. The Applicants’ claimed device has a pin engageable with a central aperture of the driving spring and is additionally disengageable from the driving spring to allow selective triggering of pressure application. To support a rejection of a claim under 35 U.S.C. § 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. The infusion device of Sage does not anticipate or

make obvious the specific pin usage and structure of the Applicants' Claims 1 and 6, as filed. Thus, Applicants submit that Claims 1 and 6 are allowable over Sage since the structure and method of Sage is different from the Applicants' claimed invention. Since there is no "pin," as used by the Applicants, in the Sage reference, there cannot be anticipation of a tactile indication by Sage as Claimed by Applicant's Claims 2 and 8. Furthermore, the pushbutton 42 of Sage serves to move the fluid access needle 54 of Sage into position, therefore, there is no anticipation of a release of a pin 140 (by pushbutton or other action) as claimed by Applicant's Claims 3-5 and 9-11. Reproduced below for the Examiner's convenience is an Annotated Exploded view (from Fig. 4 of Sage), and an annotated Exploded view of the Applicant's infusion device (from Fig 10 of instant specification)

#### Sage Reference Exploded view



#### Applicants' Exploded view



Applicants respectfully requests that the Examiner withdraw the 35 U.S.C. §102 rejections against Claims 1-11.

**New Claims**

New claims 12-20 have been added to further define aspects of the invention, which are fully supported by the instant specification. Accordingly, no new matter has been added.

New independent claim 12 has similar elements and steps as original Claim 1 in the instant application, but in addition recites the limitations of a selective fluid communication. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest a device according to the present invention. Without discussing each in detail, it will be appreciated that the claims depending from Claim 12 recite additional features that are not taught or suggested by the prior art.

**IDS filed Herewith**

Applicant respectfully submitted these communications to make of record the document cited in FORM PTO-1449 along with the fee for such an IDS. The documents submitted do not constitute an admission that they are relevant or material to the claims or are "prior art" to the subject application. The citation of the above documents should not to be considered as a representation that no better art exists or that a search has been made. In light of the above amendments, Applicant believes Claims 1-20 are novel and non-obvious over the documents cited. Consideration and prompt allowance of the claims are respectfully submitted.

## **Conclusion**

In view of the Remarks above, applicant respectfully submits that Claims 1-20 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider the rejections and objections of the present application.

Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, IDS and Extension, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted. Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

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Claim Count

	After Entry of this Amendment	Highest Number Paid (Default- 20 & 3)	Extra Claims
<b>Total Claims</b>	20	20	0
<b>Independent Claims</b>	3	3	0